DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#14

APR 6 1989

Re: Ceradon
Docket No. 89E-0086
Patent No. 4,241,057
Docket No. 89E-0087
Patent No. 4,161,527

The Honorable Donald J. Quigg
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Quigg:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 4,241,057 and 4,161,527, filed by Takeda Chemical Industries, Ltd. under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for Ceradon (cefotiam hydrochloride), the human drug product claimed by the patent.

The total length of the review period for Ceradon is 3,158 days. Of this time, 1,817 days occurred during the testing phase and 1,341 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 10, 1980.

   FDA has verified the applicant's claim that the date the investigational new drug application (IND) for Ceradon became effective was May 10, 1980.

2. The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act: April 30, 1985.

   FDA has verified the applicant's claim that the date the new drug application (NDA 50-601) was initially submitted to the FDA was on April 30, 1985.

3. The date the application was approved: December 30, 1988.

   FDA has verified the applicant's claim that NDA 50-601 was approved on December 30, 1988.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Douglas P. Mueller
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